

PREVACID 24 HR- lansoprazole capsule, delayed release
L. Perrigo Company

Prevacid 24HR Drug Facts

Active ingredient (in each capsule)

Lansoprazole 15 mg

Purpose

Acid Reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to lansoprazole

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

Inactive ingredients

colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid and ethyl acrylate copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?

1-800-864-9649

Consumer Information

Treats Frequent Heartburn

PERRIGO Selfcare

24HR

PREVACID®

Lansoprazole delayed-release capsules 15 mg/acid reducer

- May take 1 to 4 days for full effect
- Sodium Free

Please read the entire package insert before taking PREVACID®24HR.

Save for future reference.

How PREVACID®24HR Treats Your Frequent Heartburn

PREVACID®24HR stops acid production at the source – the **pumps** that release acid into the stomach. PREVACID®24HR is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking PREVACID®24HR

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take PREVACID®24HR in the morning before eating. PREVACID®24HR is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take PREVACID®24HR every day for 14 days to treat your frequent heartburn.

Who Should Take PREVACID®24HR

Adults (18 years and older) with **frequent heartburn** – when you have heartburn 2 or more days a week.

Who Should NOT Take PREVACID®24HR

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take PREVACID®24HR

14-DAY Course of Treatment

- Swallow 1 capsule with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 capsule a day.
- Swallow whole. Do not crush or chew capsules.
- Do not use for more than 14 days unless directed by your doctor.

When to Take PREVACID®24HR Again

You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to Ask Your Doctor

Allergy alert: Do not use if you are allergic to lansoprazole

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
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Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Clinical studies prove PREVACID®24HR effectively treats frequent heartburn

In three clinical studies, PREVACID®24HR was shown to be significantly better than placebo in

treating frequent heartburn.

How PREVACID®24HR is Sold

PREVACID®24HR is available in 14 capsule and 42 capsule sizes. These sizes contain one and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About PREVACID®24HR

Call 1-800-864-9649

Distributed By

Perrigo®

Allegan, MI 49010

perrigo.com

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Package/Label Principal Display Panel

Treats Frequent Heartburn

PERRIGO Selfcare

24HR

PREVACID

Lansoprazole delayed-release capsules 15 mg / acid reducer

May take 1 to 4 days for full effect

Sodium Free

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT



NDC 0113-8002-01



Drug Facts (continued)

Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

Inactive ingredients colloidal silicon dioxide, D&C red No. 28, FD&C blue No. 1, FD&C green No. 3, FD&C red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid and ethyl acrylate copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar sphere, talc, titanium dioxide

Questions or comments?
1-800-864-9649

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE.
DO NOT USE IF INNER FOIL SEAL IMPRINTED
WITH "SEALED for YOUR PROTECTION" OR
BLACK BAND AROUND THE CENTER OF EACH
CAPSULE IS MISSING OR BROKEN.

Treats Frequent Heartburn

24HR
PREVACID®

Lansoprazole delayed-release capsules 15 mg / acid reducer

- May take 1 to 4 days for full effect
- Sodium Free

14 

CAPSULES

ONE 14-DAY COURSE OF TREATMENT





PREVACID 24 HR

lansoprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-6002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)		LANSOPRAZOLE	15 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
D&C RED NO. 28 (UNII: 767IP0Y5NH)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)				
MAGNESIUM CARBONATE (UNII: 0E53J927NA)				
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
STARCH, CORN (UNII: O8232NY3SJ)				
SUCROSE (UNII: C151H8M554)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	BLUE (TEAL) , PINK	Score	no score	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code	P24HR	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-6002-01	1 in 1 CARTON	11/05/2020	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0113-6002-03	3 in 1 CARTON	11/19/2020	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA022327		11/05/2020	

Labeler - L. Perrigo Company (006013346)